

ISO 9001:1994 Versus Mil-Q-9858A Requirements Comparison

(Prepared for Training Purposes)

ISO 9001:1994 Requirement*	Mil-Q-9858A Requirement
4.1 Management responsibility	
<p>4.1.1 Quality policy</p> <p>Define and document policy for quality, including objectives for quality and its commitment to quality. The quality policy shall be relevant to the supplier's goals and the expectations and needs of its customers. Ensure that this policy is understood, implemented and maintained at all levels of the organization.</p>	<p>1.2 Contractual Intent. This specification requires the establishment of a quality program...</p> <p>Note: Mil-Q-9858A requires a program, not a system and goals.</p>
4.1.2 Organization	Not Applicable
<p>4.1.2.1 Responsibility and authority</p> <p>Define and document the responsibility, authority and the interpretation of personnel who manage, perform and verify work affecting quality, particularly for personnel who need the organizational freedom and authority to:</p> <ul style="list-style-type: none"> a) initiate action to prevent the occurrence of any nonconformities relating to the product, process and quality system; b) identify and record any problems relating to the product, process and quality system; c) initiate, recommend or provide solutions through designated channels; d) verify the implementation of solutions; e) control further processing delivery or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected. 	<p>1.3 Summary. ...The authority and responsibility of those in charge of the design, production, testing, and inspection of quality shall be clearly stated.</p> <p>3.1 Organization. Effective management for quality shall be clearly prescribed by the contractor. Personnel performing quality functions shall have sufficient, well-defined responsibility, authority and the organizational freedom to identify and evaluate quality problems and to initiate, recommend or provide solutions.</p> <p>3.5 Corrective Action. ... Corrective action shall include as a minimum:</p> <ul style="list-style-type: none"> c. Introduction of required improvements and corrections, an initial review of adequacy of such measures and monitoring of the effectiveness of corrective action taken. <p>6.2 Production Processing and Fabrication. ... Methods of inspection and monitoring shall be corrected any time their unsuitability with reasonable evidence is demonstrated.</p> <p>6.5 Nonconforming Material. The contractor shall establish and maintain an effective and positive system for controlling nonconforming material, including procedures for its identification, segregation, and disposition.</p>
<p>4.1.2.2 Resources</p> <p>Identify resource requirements and provide adequate resources, including the assignment of trained personnel (see 4.18) for management, performance of work and verification activities including internal quality audits.</p>	<p>3.2 Initial Quality Planning. The contractor, during the earliest practical phase... shall conduct a complete review of the requirements of the contract to identify ...special controls, processes, test equipment, fixtures, ...and skills required for assuring product quality.</p>
<p>4.1.2.3 Management Representative</p> <p>Appoint a member of the supplier's own management with defined authority for</p> <ul style="list-style-type: none"> a) ensuring that a quality system is established, implemented and maintained ... b) reporting on the performance of the quality system to the supplier's management for review and ... c) improvement 	<p>3.1 Organization. Effective management for quality shall be clearly prescribed by the contractor. Personnel performing quality functions shall have sufficient, well-defined responsibility, authority and the organizational freedom to identify and evaluate quality problems and to initiate, recommend or provide solutions.</p>

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<p>4.1.3 Management review</p> <p>Review the quality system at defined intervals; records shall be maintained.</p>	<p>3.1 Organization. Effective management for quality... Management regularly shall review the status and adequacy of the quality program.</p>
<p>4.2 Quality System</p>	<p>Not Applicable</p>
<p>4.2.1 General</p> <p>Establish, document and maintain a quality system as a means of ensuring that product conforms to specified requirements. Prepare a quality manual covering the requirements and including or referencing quality system procedures.</p>	<p>1.2 Contractual Intent. This specification requires the establishment of a quality program...</p>
<p>4.2.2 Quality system procedures</p> <p>Prepare documented procedures consistent with ISO 9001 and the stated quality policy, and effectively implement the quality system and its documented procedures.</p>	<p>1.2 Contractual Intent. This specification requires the establishment of a quality program... The quality program, including procedures, processes, and product shall be documented ...</p>
<p>4.2.3 Quality planning</p> <p>Define and document how the requirements for quality will be met. Quality planning must be consistent with all other requirements of a supplier's quality system and documented. giving consideration to the following activities:</p> <ul style="list-style-type: none"> a) the preparation of quality plans; b) the identification and acquisition of any controls, processes, equipment (including inspection and test equipment), fixtures, resources and skills; c) ensuring the compatibility of the design, the production process, installation, servicing, inspection and test procedures and the applicable documentation; d) the updating, as necessary, of quality control, inspection and testing techniques; e) the identification of any measurement requirement involving capability that exceeds the known state of the art; f) the identification of suitable verification at appropriate stages; <p>the clarification of standards of acceptability for all features and requirements; the identification and preparation of quality records (see 4.16).</p>	<p>3.2 Initial Quality Planning. The contractor, during the earliest practical phase... shall conduct a complete review of the requirements of the contract to identify ...special controls, processes, test equipment, fixtures, ...and skills required for assuring product quality. This initial planning will recognize the need and provide for research, when necessary, to update inspection and testing techniques ... This planning will also provide appropriate review and action to assure compatibility of manufacturing, inspection, testing and documentation.</p> <p>4.5 Advanced Metrology Requirements. The quality program shall include timely identification and report to the contracting officer of any precision measurement need exceeding the known state of the art.</p> <p>3.4 Records. The contractor shall maintain and use any records or data essential to the economical and effective operation of his quality program.</p>
<p>4.3 Contract review</p>	<p>Not Applicable</p>
<p>4.3.1 General</p> <p>Establish and maintain documented procedures for contract review and coordination of activities.</p>	<p>3.2 Initial Quality Planning. The contractor, during the earliest practical phase... shall conduct a complete review of the requirements of the contract to identify ...special controls, processes, test equipment, fixtures, ...and skills required for assuring product quality.</p>
<p>4.3.2 Review</p> <p>Review a tender, contract, or order to ensure that:</p> <ul style="list-style-type: none"> a) the requirements are adequately defined and documented; 	<p>3.2 Initial Quality Planning. The contractor, during the earliest practical phase... shall conduct a complete review of the requirements of the contract to identify ...special controls, processes, test equipment, fixtures, ...and skills required for</p>

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<p>b) any differences between the contract or order requirements and those in the tender are resolved;</p> <p>c) the capability exists to meet the contract or order requirements.</p>	<p>assuring product quality. This initial planning will recognize the need and provide for research, when necessary, to update inspection and testing techniques ... This planning will also provide appropriate review and action to assure compatibility of manufacturing, inspection, testing and documentation.</p>
<p>4.3.3 Amendment to a contract</p> <p>Identify how an amendment to a contract is made and correctly transferred to the functions concerned.</p>	<p>Not Applicable</p>
<p>4.3.4 Records</p> <p>Maintain records of contract reviews (see 4.16)</p>	<p>3.4 Records. The contractor shall maintain and use any records or data essential to the economical and effective operation of his quality program.</p>
<p>4.4 Design control</p>	<p>Not Applicable</p>
<p>4.4.1 General</p> <p>Establish and maintain documented procedures to control and verify the design of the product to ensure the specified requirements are met.</p>	<p>4.1 Drawings, Documentation and Changes. A procedure shall be maintained that concerns itself with the adequacy, the completeness of drawings and with the control of changes in design.</p>
<p>4.4.2 Design and development planning</p> <p>Prepare plans for each design and development activity that describe the activities, define responsibility for implementation, assign to qualified personnel, and update.</p>	<p>4.1 Drawings, Documentation and Changes. A procedure shall be maintained that concerns itself with the adequacy, the completeness of drawings and with the control of changes in design.</p>
<p>4.4.3 Organizational and technical interfaces</p> <p>Define, document, and review the organizational and technical interfaces with input to the design process.</p>	<p>Not Applicable</p>
<p>4.4.4 Design input</p> <p>Identify, document, and review for adequacy the design input requirements. Resolve ambiguous or conflicting requirements. Consider the contract review activities.</p>	<p>4.1 Drawings, Documentation and Changes. With respect to design drawings and design specifications, a procedure shall be maintained that shall provide for the evaluation of their engineering adequacy and an evaluation of the adequacy of proposed changes. The evaluation shall encompass both the adequacy in relation to standard engineering and design practices and the adequacy with respect to the design to which the drawing relates.</p>
<p>4.4.5 Design output</p> <p>Document design output and express in terms that can be verified and validated against design requirements. Output will meet the design input, contain acceptance criteria, and identify characteristics crucial to safe and proper functioning.</p>	<p>4.1 Drawings, Documentation and Changes. With respect to design drawings and design specifications, a procedure shall be maintained that shall provide for the evaluation of their engineering adequacy and an evaluation of the adequacy of proposed changes. The evaluation shall encompass both the adequacy in relation to standard engineering and design practices and the adequacy with respect to the design to which the drawing relates.</p>
<p>4.4.6 Design review</p> <p>Plan and conduct formal documented reviews of design results and include representatives of all functions concerned with the design. Keep records.</p>	<p>4.1 Drawings, Documentation and Changes. A procedure shall be maintained that concerns itself with the adequacy, the completeness of drawings and with the control of changes in design.</p>

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	With respect to design drawings and design specifications, a procedure shall be maintained that shall provide for the evaluation of their engineering adequacy and an evaluation of the adequacy of proposed changes.
4.4.7 Design verification Perform design verification at appropriate stages to ensure the design output meets the design input. Record design verification measures. (see 4.16).	Not Applicable
4.4.8 Design validation Perform design validation to ensure the product meets defined user needs and/or requirements.	6.3 Completed Item Inspection and Testing. The quality program shall assure that there is a system for final inspection and test of completed products. ... Final inspection and testing shall provide for reporting to designers any unusual difficulties, deficiencies or questionable conditions.
4.4.9 Design changes Identify, document, review and approve all design changes by authorized personnel before implementation.	4.1 Drawings, Documentation and Changes. A procedure shall be maintained that concerns itself with the adequacy, the completeness of drawings and with the control of changes in design.
4.5 Document and data control	Not Applicable
4.5.1 General Establish and maintain documented procedures to control all documents and data that relate to ISO 9001 requirements, standards and customer drawings.	3.3 Work Instructions. The quality program shall assure that all work affecting quality ... shall be prescribed in clear and complete documented instructions. The instructions are intended also to serve for supervising, inspecting and managing work.
4.5.2 Document and data approval and issues Review and approve documents and data for adequacy by authorized personnel prior to issue. Establish and make readily available a master list or equivalent document control procedure that identifies the current revision status of documents. This control shall ensure: a) pertinent issues of appropriate documents are available at all locations essential to the effective functioning of quality system; b) invalid and/or obsolete documents are promptly removed from all points of issue or use; c) any obsolete documents retained for legal and/or knowledge-preservation purposes are suitably identified.	3.3 Work Instructions. The quality program shall assure that all work affecting quality ... shall be prescribed in clear and complete documented instructions.... The instructions are intended also to serve for supervising, inspecting and managing work.
4.5.3 Document and data changes Review and approve documents and data by the same functions/organizations that perform the original review and approval. Designated functions/organizations shall have access to pertinent background information.	Not Applicable
4.6 Purchasing	5.0 Control of Purchases
4.6.7 General Establish and maintain documented procedures to ensure that purchase product conforms to specified requirements (see 3.1)	5.1 Responsibility. The contractor is responsible for assuring that all supplies and services procured from his suppliers (subcontractors and vendors) conform to the contract requirements.

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<p>4.6.2 Evaluation of subcontractors</p> <p>Evaluate and select subcontractors on the basis of their ability to meet subcontract requirements.</p> <p>Define the type and extent of control exercises by the supplier over subcontractors.</p> <p>Establish and maintain quality records of acceptable subcontractors (see 4.16).</p>	<p>5.1 Control of Purchases</p> <p>Responsibility. The contractor is responsible for assuring that all supplies and services procured from his suppliers (subcontractors and vendors) conform to the contract requirements. The selection of sources and the nature and extent of control exercised by the contractor shall be dependent upon the type of supplies, his supplier's demonstrated capability to perform, and the quality evidence made available. To assure an adequate and economical control of such material, the contractor shall utilize to the fullest extent objectives evidence of quality furnished by his suppliers. The inclusion of a product on the Qualified Products List only signifies that at one time the manufacturer made a product which met specification requirements. ... The effectiveness and integrity of the control of quality by his suppliers shall be assessed and reviewed by the contractor at intervals consistent with the complexity and quality of product. Inspection of products upon delivery to the contractor shall be used for assessment and review to the extent necessary for adequate assurance of quality.</p>
<p>4.6.3 Purchasing data</p> <p>Ensure purchasing documents contain data clearly describing the product order including:</p> <p>a.) Type, class, grade or other precise identification; b.) Title or other positive identification and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data; c.) Title, number and issue of the quality system applied.</p>	<p>5.2 Purchasing Data. The contractor's quality program shall not be acceptable to the Government unless the contractor requires of his subcontractors a quality effort achieving control of the quality of the services and supplies which they provide. The contractor shall assure that all applicable requirements are properly included or referenced in all purchase orders for products ultimately to apply on a Government contract. The purchase order shall contain a complete description of the supplies ordered including, by statement or reference, all applicable requirements for manufacturing, inspecting, testing, packaging, and any requirements for Government or contractor inspections, qualification or approvals. Technical requirements of the following nature must be included by statement or reference as a part of the required clear description: all pertinent drawings, engineering change orders, specifications (including inspection system or quality program requirements), reliability, safety, weight, or other special requirements, unusual test or inspection procedures or equipment and any special revision or model identification.</p>
4.6.4 Verification of purchase product	Not Applicable
<p>4.6.4.1 Supplier Verification at subcontractor's premises</p> <p>Specify verification arrangements and the method of product release in the purchasing documents (where supplier proposes to verify product at the subcontractors premises).</p>	<p>5.2 Purchasing Data.</p> <p>... The description of products ordered shall include a requirement for contractor inspection at the subcontractor or vendor source when such action is necessary to assure that the contractor's quality program effectively implements the contractor's responsibility for complete assurance</p>

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	of product quality.
<p>4.6.2 Customer verification of subcontracted product</p> <p>Where specified in the contract afford the customer the right to verify at the subcontractors premises and the suppliers premises that subcontracted product conforms to specified requirements.</p>	<p>7.0 Coordinated Government/Contractor Actions.</p> <p>7.1 Government Inspection at Subcontractor or Vendor Facilities. The Government reserves the right to inspect at source supplies or services not manufactured or performed with the contractor's facility. Government inspection shall not constitute acceptance; nor shall it in any way replace contractor inspection or otherwise relieve the contractor of his responsibility to furnish an acceptable end item.</p>
<p>4.7 Control of customer-supply product</p> <p>Establish and maintain documented procedures for the control of verification, storage and maintenance of customer-supply product provided for incorporation into supplies or related activities. Lost, damaged or unsuitable items for use shall be recorded and reported to the customer (see 4.16).</p>	<p>7.2 Government Property.</p> <p>7.2.1 Government-furnished Material.</p> <p>When material is furnished by the Government, the contractor's procedures shall include at least the following:</p> <ul style="list-style-type: none"> (a) Examination upon receipt, consistent with practicability to detect damage in transit; (b) Inspection for completeness and proper type; (c) Periodic inspection and precautions to assure adequate storage conditions and to guard against damage from handling and deterioration during storage; (d) Functional testing, either prior to or after installation, or both, as required by contract to determine satisfactory operation; (e) Identification and protection from improper use or disposition; and (f) Verification of quantity.
<p>4.8 Product identification and traceability</p> <p>Establish and maintain documented procedures for identifying the product by suitable means from receipt and during all stages of production, delivery and installation. Establish and maintain documented procedures for unique identification of individual product or batches. Record this identification (see 4.16).</p>	Not Applicable
<p>4.9 Process control</p> <p>Identify and plan the production, installation and servicing processes which directly affect quality and ensure that these processes are carried out under controlled conditions. Controlled conditions shall include the following:</p> <ul style="list-style-type: none"> a) documented procedures defining the manner of production, installation and servicing; b) use of suitable production, installation and servicing equipment, and a suitable working environment; c) compliance with reference standards/codes, quality plans and/or documented procedures; d) monitoring and control of suitable process parameters and product characteristics; e) the approval of processes and equipment; f) criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g. written standards, representative samples or illustrations); g) suitable maintenance of equipment to ensure continuing 	<p>6.2 Production Processing and Fabrication.</p> <p>The contractor's quality program must assure that all machining, wiring, batching, shaping and all basic production operations of any type together with all processing and fabricating of any type is accomplished under controlled conditions. Controlled conditions include documented work instructions, adequate production equipment, and any special working environment. Documented work instructions are considered to be the criteria for much of the production, processing and fabrication work. These instructions are the criteria for acceptable or unacceptable "workmanship". The quality program will effectively monitor the issuance of and compliance with all of these work instructions.</p> <p>Physical examination, measurement or tests of the material or products processed is necessary for</p>

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<p>process capability.</p> <p>Where the results of processes cannot be fully verified by subsequent inspection and testing of the product and where, for example, processing deficiencies may become apparent only after the product is in use, the processes shall be carried out by qualified operators and/or shall require continuous monitoring and control of process parameters to ensure that the specified requirements are met.</p> <p>Specify requirements for any qualification of process operations, including associated equipment and personnel (see 4.18).</p> <p>Records shall be maintained for qualified processes, equipment and personnel, as appropriate (see 4.16).</p>	<p>each work operation and must also be conducted under controlled conditions. If physical inspection of processed material is impossible or disadvantageous, indirect control by monitoring processing methods, equipment and personnel shall be provided. Both physical inspection and process monitoring shall be provided when control is inadequate without both, or when contract or specification requires both.</p> <p>Inspection and monitoring of processed material or products shall be accomplished in any suitable systematic manner selected by the contractor. Methods of inspection and monitoring shall be corrected any time their unsuitability with reasonable evidence is demonstrated. Adherence to selected methods for inspection and monitoring shall be complete and continuous. Corrective measures shall be taken when noncompliance occurs.</p> <p>Inspection by machine operators, automated inspection gages, moving line or lot sampling, setup or first piece approval, production line inspection station, inspection or test department, roving inspectors—any other type of inspection—shall be employed in any combination desired by the contractor which will adequately and efficiently protect product quality and the integrity of processing.</p> <p>Criteria for approval and rejection shall be provided for all inspection of product and monitoring of methods, equipment, and personnel. Means for identifying approved and rejected product shall be provided.</p> <p>Certain chemical, metallurgical, biological, sonic, electronic, and radiological processes are of so complex and specialized a nature that much more than the ordinary detailing of work documentation is required. In effect, such processing may require an entire work specification as contrasted with the normal work operation instructions established in normal plant-wide standard production control issuances such as job operation routing books and the like. For these special processes, the contractors' quality program shall assure that the process control procedures or specifications are adequate and that processing environments and the certifying, inspection, authorization and monitoring of such processes to the special degree necessary for these ultra precise and super-complex work functions are provided.</p>
4.10 Inspection and testing	Not Applicable
<p>4.10.1 General</p> <p>Establish and maintain documented procedures for inspection and testing activities in order to verify that the specified requirements for the product are met. The</p>	<p>6.1 Materials and Materials Control.</p> <p>Supplier's materials and products shall be subjected to inspection upon receipt to the extent necessary to assure conformance to technical requirements. Receiving inspection may be</p>

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required inspection and testing, and the records to be established, shall be detailed in the quality plan or documented procedures.	adjusted upon the basis of the quality assurance program exercised by suppliers. Evidence of the supplier's satisfactory control of quality may be used to adjust the amount and kind of receiving inspection.
4.10.2 Receiving Inspection and testing	Not Applicable
4.10.2.1 Ensure that incoming product is not used or processed (except in the circumstances described in until it has been inspected or otherwise verified as conforming to specified requirements. Verification of conformance to the specified requirements shall be in accordance with the quality plan and/or documented procedures.	<p>6.1 Materials and Materials Control. Supplier's materials and products shall be subjected to inspection upon receipt to the extent necessary to assure conformance to technical requirements. Receiving inspection may be adjusted upon the basis of the quality assurance program exercised by suppliers. Evidence of the supplier's satisfactory control of quality may be used to adjust the amount and kind of receiving inspection.</p> <p>The quality program shall assure that raw materials to be used in fabrication or processing of products conform to the applicable physical, chemical, and other technical requirements. Laboratory testing shall be employed as necessary. Suppliers shall be required by the contractor's quality program to exercise equivalent control of the raw materials utilized in the production of the parts and items which they supply to the contractor. Raw material awaiting testing must be separately identified or segregated from already tested and approved material but can be released for initial production, providing that identification and control is maintained. Material tested and approved must be kept identified until such time as its identity is necessarily obliterated by processing. Controls will be established to prevent the inadvertent use of material failing to pass tests.</p>
4.10.2.2 In determining the amount and nature of receiving inspection, consideration shall be given to the amount of control exercised at the subcontractor's premises and the recorded evidence of conformance provided.	6.1 Materials and Materials Control. Supplier's materials and products shall be subjected to inspection upon receipt to the extent necessary to assure conformance to technical requirements. Receiving inspection may be adjusted upon the basis of the quality assurance program exercised by suppliers. Evidence of the supplier's satisfactory control of quality may be used to adjust the amount and kind of receiving inspection.
4.10.2.3 Where incoming product is released for urgent production purposes prior to verification, it shall be positively identified and recorded (see 4.16) in order to permit immediate recall and replacement in the event of nonconformity to specified requirements.	Not Applicable
<p>4.10.3 In-process inspection and testing</p> <p>Inspect and test the product as required by the quality plan and/or documented procedures;</p> <p>Hold product until the required inspection and tests have</p>	6.2 Production Processing and Fabrication. The contractor's quality program must assure that all machining, wiring, batching, shaping and all basic production operations of any type together with all processing and fabricating of any type is accomplished under controlled conditions...

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<p>been completed or necessary reports have been received and verified, except when product is released under positive-recall procedures (see 4.10.2.3).</p>	<p>Physical examination, measurement or tests of the material or products processed is necessary for each work operation and must also be conducted under controlled conditions. If physical inspection of processed material is impossible or disadvantageous, indirect control by monitoring processing methods, equipment and personnel shall be provided. Both physical inspection and process monitoring shall be provided when control is inadequate without both, or when contract or specification requires both.</p> <p>Inspection and monitoring of processed material or products shall be accomplished in any suitable systematic manner selected by the contractor. Methods of inspection and monitoring shall be corrected any time their unsuitability with reasonable evidence is demonstrated. Adherence to selected methods for inspection and monitoring shall be complete and continuous. Corrective measures shall be taken when noncompliance occurs.</p> <p>Inspection by machine operators, automated inspection gages, moving line or lot sampling, setup or first piece approval, production line inspection station, inspection or test department, roving inspectors—any other type of inspection—shall be employed in any combination desired by the contractor which will adequately and efficiently protect product quality and the integrity of processing.</p> <p>Criteria for approval and rejection shall be provided for all inspection of product and monitoring of methods, equipment, and personnel. Means for identifying approved and rejected product shall be provided.</p>
<p>4.10.4 Final inspection and testing</p> <p>Carry out all final inspection and testing in accordance with the quality plan and/or documented procedures to complete the evidence of conformance of the finished product to the specified requirements.</p> <p>The quality plan and/or documented procedures for final inspection and testing shall require that all specified inspection and tests, including those specified either on receipt of product or in-process, have been carried out and that the results meet specified requirements.</p> <p>No product shall be dispatched until all the activities specified in the quality plan and/or documented procedures have been satisfactorily completed and the associated data and documentation are available and authorized.</p>	<p>6.3 Completed Item Inspection and Testing. The quality program shall assure that there is a system for final inspection and test of completed products. Such testing shall provide a measure of the overall quality of the completed product and shall be performed so that it simulates, to a sufficient degree, product end use and functioning. Such simulation frequently involves appropriate life and endurance tests and qualification testing. Final inspection and testing shall provide for reporting to designers any unusual difficulties, deficiencies or questionable conditions. When modifications, repairs or replacements are required after final inspection or testing, there shall be re-inspection and re-testing of any characteristics affected.</p>
<p>4.10.5 Inspection and test records</p> <p>Establish and maintain records which provide evidence</p>	<p>3.4 Records. The contractor shall maintain and use any records or data essential to the economical and effective operation of his quality program.</p>

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that the product has been inspected and/or tested. These records shall show clearly whether the product has passed or failed the inspections and/or tests according to defined acceptance criteria. Where the product fails to pass any inspection and/or test, the procedures for control of nonconforming product shall apply (see 4.16).	These records shall be available for review by the Government Representative and copies of individual records shall be furnished him upon request. Records are considered one of the principal forms of objective evidence of quality. The quality program shall assure that records are complete and reliable. Inspection and testing records shall, as a minimum, indicate the nature of the observations together with the number of observations made and the number and type of deficiencies found. Also, records for monitoring work performance and for inspection and testing shall indicate the acceptability of work or products and the action taken in connection with deficiencies. The quality program shall provide for the analysis and use of records as a basis for management action.
4.11 Control of inspection, measuring and test equipment	Not Applicable
<p>4.11.1 General</p> <p>Establish and maintain documented procedures to control, calibrate and maintain inspection, measuring and test equipment (including test software) used by the supplier to demonstrate the conformance of product to demonstrate the conformance of product to the specified requirements. Inspection, measuring and test equipment shall be used in a manner which ensures that the measurement uncertainty is known and is consistent with the required measurement capability.</p> <p>Where test software or comparative references such as test hardware are used as suitable forms of inspection, they shall be checked to prove that they are capable of verifying the acceptability of product, prior to release for use during production, installation, or servicing, and shall be rechecked at prescribed intervals. The supplier shall establish the extent and frequency of such checks and shall maintain records as evidence of control (see 4.16).</p> <p>Where the availability of technical data pertaining to the inspection, measuring and test equipment is a specified requirement, such data shall be made available, when required by the customer or customer's representative, for verification that the inspection, measuring and test equipment is functionally adequate.</p>	<p>4.0 Facilities and Standards.</p> <p>4.2 Measuring and Testing Equipment. The contractor shall provide and maintain gages and other measuring and testing devices necessary to assure that supplies conform to technical requirements. These devices shall be calibrated against certified measurement standards which have known valid relationships to national standards at established periods to assure continued accuracy. The objective is to assure that inspection and test equipment is adjusted, replaced or repaired before it becomes inaccurate. The calibration of measuring and testing equipment shall be in conformity with military specification Mil-C-45662. In addition, the contractor shall ensure the use of only such subcontractor and vendor sources that depend upon calibration systems which effectively control the accuracy of measuring and testing equipment.</p> <p>4.3 Production Tooling Used as Media of Inspection. When production jigs, fixtures, tooling masters, templates, patterns and such other devices are used as media of inspection, they shall be proved for accuracy prior to release for use. These devices shall be proved again for accuracy at intervals formally established in a manner to cause their timely adjustment, replacement or repair prior to becoming inaccurate.</p> <p>4.4 Use of Contractor's Inspection Equipment. The contractor's gages, measuring and testing devices shall be made available for use by the Government when required to determine conformance with contract requirements. If conditions warrant, contractor's personnel shall be made available for operation of such devices and for verification of their accuracy and condition.</p>

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<p>4.11.2 Control procedure</p> <p>Determine the measurements to be made and the accuracy required, and select the appropriate inspection, measuring and test equipment that is capable of the necessary accuracy and precision;</p> <p>Identify all inspection, measuring and test equipment that can affect product quality, and calibrate and adjust them at prescribed intervals, or prior to use, against certified equipment having a known valid relationship to internationally or nationally recognized standards. Where no such standards exists, the basis used for calibration shall be documented;</p> <p>Define the process employed for the calibration of inspection, measuring and test equipment, including details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria and the action to be taken when results are unsatisfactory;</p> <p>Identify inspection, measuring and test equipment with a suitable indicator or approved identification record to show the calibration status;</p> <p>Maintain calibration records for inspection, measuring and test equipment (see 4.16);</p> <p>Assess and document the validity of previous inspection and test results when inspection, measuring or test equipment is found to be out of calibration;</p> <p>Ensure that the environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out;</p> <p>Ensure that the handling, preservation and storage of inspection, measuring and test equipment is such that the accuracy and fitness for use are maintained;</p> <p>Safeguard inspection, measuring and test facilities, including both test hardware and test software, from adjustments which would invalidate the calibration setting.</p>	<p>Note: Refer to Mil-C-45662A for comparison.</p>
<p>4.12 Inspection and test status</p> <p>Identify the inspection and test status of product by suitable means, which indicate the conformance or nonconformance of product with regard to inspection and test performed. Maintain the identification of inspection and test status, as defined in the quality plan and/or documented procedures, throughout production, installation and servicing of the product to ensure that only product that has passed the required inspections and tests [or released under an authorized concession (see 4.13.2)] is</p>	<p>6.7 Indication of Inspection Status. The contractor shall maintain a positive system for identifying the inspection status of products. Identification may be accomplished by means of stamps, tags, routing cards, move tickets, tote box cards or other normal control devices. Such controls shall be of a design distinctly different from Government inspection identification.</p>

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dispatched, used or installed.	
4.13 Control of nonconforming product	Not Applicable
<p>4.13.1 General</p> <p>Establish and maintain documented procedures to ensure that product that does not conform to specified requirements is prevented from unintended use or installation. This control shall provide for identification, documentation, evaluation, segregation (when practical), disposition of nonconforming product and for notification to the functions concerned.</p>	<p>6.5 Nonconforming Material. The contractor shall establish and maintain an effective and positive system for controlling nonconforming material, including procedures for its identification, segregation, and disposition. ... All nonconforming supplies shall be positively identified to prevent unauthorized use, shipment and intermingling with conforming supplies. Holding areas or procedures mutually agreeable to the contractor and the Government Representative shall be provided by the contractor. The contractor shall make known to the Government upon request the data associated with the costs and losses in connection with scrap and with rework necessary to reprocess nonconforming material to make it conform completely.</p> <p>Note: Also, see Mil-STD-1520.</p>
<p>4.13.2 Review and disposition of nonconforming product</p> <p>Define the responsibility for review and authority for the disposition of nonconforming product.</p> <p>Review nonconforming product in accordance with documented procedures. It may be</p> <p>a) reworked to meet the specified requirements, b) accepted with or without repair by concession, c) regraded for alternative applications, or d) rejected or scrapped.</p> <p>Where required by the contract, the proposed use or repair of product [see 4.13.2b)] which does not conform to specified requirements shall be reported for concession to the customer or customer's representative. The description of the nonconformity that has been accepted, and of repairs, shall be recorded to denote the actual condition (see 4.16).</p> <p>Repaired and/or reworked product shall be re-inspected in accordance with the quality plan and/or documented procedures.</p>	<p>6.5 Nonconforming Material. The contractor shall establish and maintain an effective and positive system for controlling nonconforming material, including procedures for its identification, segregation, and disposition. Repair or rework of nonconforming material shall be in accordance with documented procedures acceptable to the Government. The acceptance of nonconforming supplies is a prerogative of and shall be as prescribed by the Government and may involve a monetary adjustment. All nonconforming supplies shall be positively identified to prevent unauthorized use, shipment and intermingling with conforming supplies. Holding areas or procedures mutually agreeable to the contractor and the Government Representative shall be provided by the contractor. The contractor shall make known to the Government upon request the data associated with the costs and losses in connection with scrap and with rework necessary to reprocess nonconforming material to make it conform completely.</p>
4.14 Corrective and preventive action	Not Applicable
<p>4.14.1 General</p> <p>Establish and maintain documented procedures for implementing corrective and preventive action.</p> <p>Any corrective or preventive action taken to eliminate the causes of actual or potential nonconformities shall be to a degree appropriate to the magnitude of problems and commensurate with the risks encountered.</p>	<p>3.0 Quality Program Management</p> <p>3.5 Corrective Action. The quality program shall detect promptly and correct assignable conditions adverse to quality. Design, purchasing, manufacturing, testing or other operations which could result in or have resulted in defective supplies, services, facilities, technical data, standards or other elements of contract performance which could create excessive losses or costs must be identified and changed as a result of the quality</p>

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Implement and record any changes to the documented procedures resulting from corrective and preventive action.	program. Corrective action will extend to the performance of all suppliers and vendors and will be responsive to data and product forwarded from users.
<p>4.14.2 Corrective action</p> <p>The procedures for corrective action shall include:</p> <p>a) the effective handling of customer complaints and reports of product nonconformities;</p> <p>b) investigation of the cause of nonconformities relating to product, process and quality system, and recording the results of the investigation (see 4.16);</p> <p>c) determination of the corrective action needed to eliminate the cause of nonconformities;</p> <p>d) application of controls to ensure that corrective action is taken and that it is effective.</p>	<p>3.5 Corrective Action. ... Corrective action shall include as a minimum:</p> <p>(a) Analysis of data and examination of product scrapped or reworked to determine extent and causes;</p> <p>(b) Analysis of trends in processes or performance of work to prevent nonconforming product; and</p> <p>(c) Introduction of required improvements and corrections, an initial review of adequacy of such measures and monitoring of the effectiveness of corrective action taken.</p>
<p>4.14.3 Preventive action</p> <p>The procedures for preventive action shall include:</p> <p>a) the use of appropriate sources of information such as processes and work operations which affect product quality, concessions, audit results, quality records, service reports and customer complaints to detect, analyze and eliminate potential causes of nonconformities;</p> <p>b) determination of the steps needed to deal with any problems requiring preventive action;</p> <p>c) initiation of preventive action and application of controls to ensure that it is effective;</p> <p>d) ensuring that relevant information on actions taken is submitted for management review (see 4.1.3).</p>	<p>3.5 Corrective Action. ... Corrective action shall include as a minimum:</p> <p>(a) Analysis of data and examination of product scrapped or reworked to determine extent and causes;</p> <p>(b) Analysis of trends in processes or performance of work to prevent nonconforming product; and</p> <p>(c) Introduction of required improvements and corrections, an initial review of adequacy of such measures and monitoring of the effectiveness of corrective action taken.</p>
4.15 Handling, storage, packaging, preservation and delivery	Not Applicable
<p>4.15.1 General</p> <p>Establish and maintain documented procedures for handling, storage, packaging, preservation and delivery of product.</p>	<p>6.0 Manufacturing Control.</p> <p>6.4 Handling, Storage and Delivery. The quality program shall provide for adequate work and inspection instruction for handling, storage, preservation, packaging, and shipping to protect the quality of products and prevent damage, loss, deterioration, degradation, or substitution of products.</p>
<p>4.15.2 Handling</p> <p>Provide methods of handling product that prevent damage or deterioration.</p>	<p>6.4 Handling, Storage and Delivery. ... With respect to handling, the quality program shall require and monitor the use of procedures to prevent handling damage to articles. Handling procedures of this type include the use of special crates, boxes, containers, transportation vehicles and any other facilities for materials handling.</p>
<p>4.15.3 Storage</p> <p>Use designated storage areas or stock rooms to prevent damage or deterioration of product, pending use or delivery. Appropriate methods for authorizing receipt to and dispatch from such areas shall be stipulated.</p>	<p>6.4 Handling, Storage and Delivery. ... Means shall be provided for any necessary protection against deterioration or damage to products in storage. Periodic inspection for the prevention and results of such deterioration or damage shall be provided. Products subject to deterioration or</p>

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In order to detect deterioration, the condition of product in stock shall be assessed at appropriate intervals.	corrosion during fabrication or interim storage shall be cleaned and preserved by methods which will protect against deterioration or corrosion.
<p>4.15.4 Packaging</p> <p>Control packing, packaging and marking processes (including materials used) to the extent necessary to ensure conformance to specified requirements.</p>	<p>6.4 Handling, Storage and Delivery. ...When necessary, packaging designing and packaging shall include means for accommodating and maintaining critical environments within packages, e.g., moisture content levels, gas pressures. The quality program shall assure that when such packaging environments must be maintained, packages are labeled to indicate this condition.</p>
<p>4.15.5 Preservation</p> <p>Apply appropriate methods for preservation and segregation of product when the product is under the supplier's control.</p>	<p>6.4 Handling, Storage and Delivery. The quality program shall provide for adequate work and inspection instruction for handling, storage, preservation, packaging, and shipping to protect the quality of products and prevent damage, loss, deterioration, degradation, or substitution of products.</p> <p>5.2 Purchasing Data. ... The purchase order shall contain a complete description of the supplies ordered including, by statement or reference, all applicable requirements for manufacturing, inspecting, testing, packaging, and any requirements for Government or contractor inspections, qualification or approvals.</p>
<p>4.15.6 Delivery</p> <p>Arrange for the protection of the quality of product after final inspection and test. Where contractually specified, this protection shall be extended to include delivery to destination.</p>	<p>6.4 Handling, Storage and Delivery. ...The quality program shall monitor shipping work to assure that products shipped are accompanied with required shipping and technical documents and that compliance with Interstate Commerce Commission rules and other applicable shipping regulations is effected to assure safe arrival and identification at destination. In compliance with contractual requirements, the quality program shall include monitoring provisions for protection of the quality of products during transit.</p>
<p>4.16 Control of quality records</p> <p>Establish and maintain documented procedures for identification, collection, indexing, access, filing, storage, maintenance and disposition of quality records.</p> <p>Maintain Quality records to demonstrate conformance to specified requirements and the effective operation of the quality system. Pertinent quality records from the subcontractor shall be an element of these data.</p> <p>All quality records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of quality records shall be established and recorded. Where agreed contractually, quality records shall be made available for evaluation by the customer or the customer's representative for an agreed period.</p>	<p>3.0 Quality Program Management.</p> <p>3.4 Records. The contractor shall maintain and use any records or data essential to the economical and effective operation of his quality program. These records shall be available for review by the Government Representative and copies of individual records shall be furnished him upon request. Records are considered one of the principal forms of objective evidence of quality. The quality program shall assure that records are complete and reliable. Inspection and testing records shall, as a minimum, indicate the nature of the observations together with the number of observations made and the number and type of deficiencies found. Also, records for monitoring work performance and for inspection and testing shall indicate the acceptability of work or products and the action taken in connection with deficiencies. The quality program shall provide for</p>

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	the analysis and use of records as a basis for management action.
<p>4.17 Internal quality audits</p> <p>Establish and maintain documented procedures for planning and implementing internal quality audits to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system.</p> <p>Schedule internal quality audits on the basis of the status and importance of the activity to be audited and shall be carried out by personnel independent of those having direct responsibility for the activity being audited.</p> <p>Record and bring the results of the audits (see 4.16) to the attention of the personnel having responsibility in the area audited. The management personnel responsible for the area shall take timely corrective action on deficiencies found during the audit.</p> <p>Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken (see 4.16).</p>	<p>3.0 Quality Program Management.</p> <p>3.1 Organization. Effective management for quality... Management regularly shall review the status and adequacy of the quality program.</p> <p>Note: Mil-Q-9858A does not explicitly call for an internal audit program or procedures.</p>
<p>4.18 Training</p> <p>Establish and maintain documented procedures for identifying training needs and provide for the training of all personnel performing activities affecting quality. Personnel performing specific assigned tasks shall be qualified on the basis of appropriate education, training and/or experience, as required. Appropriate records of training shall be maintained (see 4.16).</p>	<p>3.0 Quality Program Management.</p> <p>3.2 Initial Quality Planning. The contractor, during the earliest practical phase... shall conduct a complete review of the requirements of the contract to identify ...special controls, processes, test equipments, fixtures, ...and skills required for assuring product quality.</p> <p>Note: Mil-Q-9858A does not explicitly call for an training program or procedures.</p>
<p>4.19 Servicing</p> <p>Where servicing is a specified requirement, establish and maintain documented procedures for performing, verifying and reporting that the servicing meets the specified requirements.</p>	Not Applicable
4.20 Statistical techniques	Not Applicable
<p>4.20.1 Identification of need</p> <p>Identify the need for statistical techniques required for establishing, controlling and verifying process capability and product characteristics.</p>	6.6 Statistical Quality Control and Analysis. In addition to statistical methods required by the contract, statistical planning, analysis, tests and quality control procedures may be utilized whenever such procedures are suitable to maintain the required control of quality.
<p>4.20.2 Procedures</p> <p>Establish and maintain documented procedures to implement and control the application of the statistical techniques identified in 4.20.1.</p>	6.6 Statistical Quality Control and Analysis. ... Sampling plans may be used when tests are destructive, or when the records, inherent characteristics of the product or the noncritical application of the product, indicate that a reduction in inspection or testing can be achieved without jeopardizing quality. The contractor may employ sampling inspection in accordance with applicable

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	military standards and sampling plans (e.g., from MIL-STD-105, MIL-STD-414, or Handbooks H 106, 107 and 108). If the contractor uses other sampling plans, they shall be subject to review by the cognizant Government Representative. Any sampling plan used shall provide valid confidence and quality levels.

***Note:** This matrix is intended for training purposes. The ISO 9001:1994 requirements are taken from ISO 9001:1994 Quality Systems - Model for quality assurance in design, development, production, installation and servicing. The requirements have been condensed for purposes of this training. The Mil-Q-9858A requirements are considered a best interpretative match against the ISO 9001 requirements.